## BACKGROUND
## NATURAL HISTORY OF CHRONIC HCV INFECTION

Following infection with the hepatitis C virus (HCV), chronic infection typically occurs, with approximately 50 to 85 percent of cases developing chronic hepatitis. However, chronic HCV infection usually progresses slowly and may not result in clinically apparent liver disease in many patients. Approximately 5 to 30 percent of chronically infected individuals develop cirrhosis over a 20- to 30-year period of time. In the United States, chronic HCV is the most common cause of chronic liver disease and the most frequent indication for liver transplantation.

Although many patients with chronic HCV infection are symptomatic, most symptoms are nonspecific and not clearly a result of HCV infection itself. Even if cirrhosis develops, many patients have only nonspecific symptoms. Some patients have extrahepatic findings (such as cryoglobulinemia, renal disease, or specific dermatologic disorders) that are directly related to HCV infection. There is wide variability in serum aminotransferase levels in patients with chronic HCV infection over time. Up to one-third of patients have normal levels. Occasionally, acute increases in the serum aminotransferases can occur during chronic HCV infection without apparent alternate cause. HCV RNA levels generally remain constant during chronic infection with <1 log fluctuation.

Patients who develop cirrhosis are at further risk for complicating events (such as variceal hemorrhage, ascites, and encephalopathy) and hepatocellular carcinoma, although many patients with compensated cirrhosis remain stable for years. Overall survival is decreased in patients with chronic HCV infection, especially in those who have developed cirrhosis. The baseline level of liver fibrosis is an important clinical predictor of further fibrosis progression. Patients with no fibrosis and minimal hepatic inflammation have a very low risk of progressing to cirrhosis. Once an individual has developed advanced fibrosis (i.e. bridging fibrosis or METAVIR stage F3), the risk of progression to cirrhosis is approximately 10 percent per year. Host factors that appear to be adversely associated with fibrosis progression in individual HCV-infected patients are older age, male gender, non-black race, alcohol use, and comorbidities such as obesity or viral coinfection. The impact of viral factors (such as genotype or diversity) is less evident.

Chopra MD. Clinical Manifestations and Natural History of Chronic Hepatitis C Virus Infection. UpToDate/ Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on January 11, 2019)

## PURPOSE

POLICY: The North Carolina Department of Public Safety, Adult Correction Division/Health Services Section recognizes the treatment of Hepatitis C is ever evolving. We will adopt the below procedures to provide interim guidance to primary care providers in the Division of Prisons Health Services on how to manage Hepatitis C until detailed guidelines have been updated and finalized.

## PROCEDURE

**Step 1**

Appropriately screen offenders for Hepatitis C. If a risk factor is present OR if offender requests, test for Hepatitis C. HCV ab (anti-HCV) #140659 or Hepatitis Panel #322744, must be ordered.

Risk factors include, but are not limited to, the following:

- Any person born between 1945 and 1965
- Chronic hemodialysis or ever received hemodialysis
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV
- History of illicit intravenous drug use
- Received tattoos or body piercings while in jail or prison
- HIV-infected or chronic HBV infection
- Received a blood transfusion or organ transplant before 1992, or received clotting factors prior to 1987
- History of percutaneous exposure to blood
- History of alcoholism or having other liver disease

**Step 2**

Provide initial medical follow up for anti-HCV positive offenders.

- All anti-HCV positive offenders will be counseled about:
    a. Natural history of HCV
    b. Risks of transmission to others
    c. Lifestyle changes that can minimize disease progression
- Take a medical history and perform a physical examination
- Try to establish duration of HCV infection by history
- Obtain baseline labs (HIV/Hepatitis Panel (if not done during screening)/CBC with diff/Complete metabolic panel/TSH/T4/PT/INR/Ferritin/Iron Saturation)
- Obtain Hepatitis C viral load (RNA) #550080
- Initiate preventive health measures as indicated: Hepatitis B vaccine, Hepatitis A vaccine, Pneumococcal vaccine, influenza vaccine

**Step 3**

Conduct pre-treatment evaluation

- Review lab results

- If HCV RNA is undetectable then there is an absence of chronic infection and, therefore, treatment is not needed. Repeat HCV RNA in 3-6 months and, if still negative, the offender has cleared infection and no longer needs to be monitored.
- All female offenders with chronic HCV of childbearing potential must have a pregnancy test. If considered for treatment, she will need a pregnancy test monthly until 6 months after treatment is complete.
- Treatment during pregnancy is not recommended.
- Determine if patient is amenable to treatment
- If patient has evidence of cirrhosis, then screen for hepatocellular carcinoma with ultrasound and AFP

**Step 4a**

- Refer all offenders with chronic Hepatitis C to the Hepatitis C Committee (comprised of the medical director, the deputy medical director, a Utilization Review physician, and Infectious Disease Nurse Clinician at a minimum).
- Hepatitis C Committee will meet monthly to evaluate cases and prioritize treatment based on current Federal Bureau of Prisons prioritization criteria
- Specific recommendations will be made to provider for the offender including but not limited to whether to obtain further labs (HCV genotype), submit referral to hepatology for treatment, or continue to monitor offender onsite

**Step 4b**

Monitor HCV- infected offenders who have not initiated treatment

- At a minimum of every 6 months, offender will be evaluated clinically for signs/symptoms of liver
  decompensation
- At a minimum of every 6 months, CBC with diff, complete metabolic panel, and INR labs will be obtained and reviewed
- Hepatitis C Committee will continue to monitor offender until enters treatment

Anita Wilson MD — **3/1/2019**

Anita Wilson, MD Medical Director — Date

SOR: Medical Director

## Table 1: *Some drugs that may cause liver damage:

**Drugs that may cause ACUTE DOSE-DEPENDENT LIVER DAMAGE (resembling acute viral hepatitis)**

- acetaminophen
- salicylates (doses over 2 grams daily)

**Drugs that may cause ACUTE DOSE-INDEPENDENT LIVER DAMAGE (resembling acute viral hepatitis)**

- acebutolol
- indomethacin
- phenylbutazone
- allopurinol
- isoniazid
- phenytoin
- atenolol
- ketoconazole
- piroxicam
- carbamazepine
- labetalol
- probenecid
- cimetidine
- maprotiline
- pyrazinamide
- dantrolene
- metoprolol
- quinidine
- diclofenac
- mianserin
- quinine
- diltiazem
- naproxen
- ranitidine
- enflurane
- para-aminosalicylic acid
- sulfonamides
- ethambutol
- penicillins
- sulindac
- ethionamide
- phenelzine
- tricyclic antidepressants
- halothane
- phenindione
- valproic acid
- ibuprofen
- phenobarbital
- verapamil

***Please refer to up-to-date (online resource) for more extensive list**

**North Carolina Division of Prisons**

**Health Services Hepatitis C Therapy**

**Informed Consent**

**(adapted from U. S. Department of Justice – Federal Bureau of Prisons)**

*After discussing each item with the inmate, the health care provider should have the inmate initial all lines and provide signature at the end.*

I,_____, OPUS No._____hereby authorize DPS Provider or DPS designated provider to prescribe treatment for Hepatitis C virus infection ( HCV) with medication.

1. ____ Your health care provider will prescribe the regimen that is most appropriate for your condition. This regimen may consist of a combination of HCV antivirals that could include: Daclatasivir, Sofosbuvir, Simeprevir, Ledipasvir/Sofosbuvir (Harvoni), Elbasvir/grazoprevir (Zepatier), Glecaprevir/pibrentasvir (Mavyret), Sofosbuvir/velpatasvir (Epclusa), ribavirin, Sofosbuvir/velpatasvir/voxilaprevir (Vosevi) or other direct acting antiviral therapy. I understand my medical condition and why this combination of medications is being recommended to treat my disease.
2. ____ This treatment requires frequent visits to the Health Services Unit for outpatient visits, blood tests, and pill line administration of the medications. Attending these appointments and adhering to the treatment regimens are essential to achieve a safe and successful treatment result.

Prior to starting treatment,each patient must assess their ability and willingness to comply with the treatment regimen described by their health care provider.In some cases,postponing treatment may be acceptable or even preferred.You may be moved to a different facility forcompleting thistreatment.

3. ____ It is important to abstain from illicit drug or alcohol use and from receiving tattoos, which may interfere with medication treatments, worsen liver disease, or increase the risk for reinfection with HCV or other infections

4. ____ To ensure continuity of care and provide the best opportunity for a successful outcome, a medical hold status that prevents your transfer to another institution may be placed until the course of therapy is complete.

<u>For patients treated with ribavirin, the following applies:</u>

5. ____ Ribavirin can cause birth defects. Both women and men, particularly those awaiting release, must be counseled to use adequate birth control (2 forms of birth control) during treatment and 6 months after treatment is completed.
6. ____ Ribavirin should not be taken if you have severe kidney dysfunction.
7. ____ Between 5%-10% of the patients taking ribavirin therapy develop anemia

within 1 to 4 weeks of beginning treatment. You should immediately speak to your doctor if you experience any side effects, or you experience trouble breathing, chest pain, severe stomach or lower back pain, bloody diarrhea or bloody bowel movements, high fever, bruising, bleeding, decreased vision, weight loss, rashes, or other symptoms that concern you.

8. ____ To improve your comfort and the chances of successfully completing this course of treatment, you should get plenty of rest, exercise lightly but regularly, drink plenty of water or clear fluids every day, eat regularly, and take acetaminophen for fevers and "flu- like" symptoms.

Physician Signature _____

Based upon interview, assessment, and medical record review, it is my opinion that this patient understands the proposed treatment, the risks and benefits of the treatment, and **is competent** to give consent.

Other issues discussed:

I certify that I have read the foregoing or have had it explained to me in a language that I understand; that I have no additional questions; and that I consent to treatment. I understand that I may stop taking this medication by contacting the physician. However, I understand that discontinuing the medication may result in failure to control the progression of liver disease.

**Inmate Signature: _____**
**OPUS No.: _____ Date: _____**
**Witness Signature: _____ Date: _____**
**Attending Physician: _____**
(Revised DC 475 1/2019)